

## **VI.2 Elements for a public summary**

### ***VI.2.1 Overview of disease epidemiology***

#### **Meniere's disease**

Approximately 3,000 Danes are affected by the disease. The disease is localized to the inner ear, consisting of the cochlea and the vestibular organ (semicircular canals). The disease causes a sudden and unexplained pressure changes in the inner ear, with resultant fluctuating hearing loss, vertigo and ringing in the ear. The disease most commonly affects only one ear, but may in some cases affect the other ear later in life. The disease can occur at any age, but materialize especially in middle age. Women and men are affected with equal frequency.

### ***VI.2.2 Summary of treatment benefits***

Betahistine Alternova acts by enhancing blood flow in the inner ear, thereby reducing the pressure in the ear. The effect of betahistine may also involve central nervous system network at various levels. Compared with other drugs used for this disease, betahistine has the advantage of being relatively free of sedative properties that could otherwise interfere with clinical improvement.

### ***VI.2.3 Unknowns relating to treatment benefits***

No data are available on use of betahistine in children below 18 years of age or in pregnant or breastfeeding women.

#### VI.2.4 *Summary of safety concerns*

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
<b>Use in children below 18 years of age</b>	There is insufficient knowledge about the efficacy and risks when treating children with betahistine.	The product is not indicated for children.
<b>Use under pregnancy and lactation</b>	There is insufficient knowledge about the risks when treating women during pregnancy and lactation.	Betahistine should only be used during pregnancy when absolutely essential.  It is unknown whether or not betahistine is expressed in breast milk. The advantage to the mother of using betahistine under breast feeding should therefore be balanced against the advantages of breast feeding and the potential risk to the child.

#### VI.2.5 *Summary of additional risk minimisation measures by safety concern*

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Betahistin Alternova can be found on the homepage of the Danish Health and Medicines Agency after the product has been approved.

This medicine has no additional risk minimisation measures.

#### VI.2.6 *Planned post authorisation development plan (if applicable)*

Not Applicable.

#### VI.2.7 *Summary of changes to the risk management plan over time*

Not Applicable.